

REMARKS

Claims 18-20 and 32-38 are currently pending in this patent application. Applicants are herein amending claim 18. Applicants gratefully acknowledge the indication that claims 34 and 37 recite allowable subject matter.

Claim Amendment

Applicants are herein amending claim 18 to add the word “tablet” to the end of the phrase “compressing the first, second and third layers into a capsule-shaped osmotic”, thereby correcting the mistaken omission of that word.

Applicants respectfully submit that no new matter is introduced by the amendments to claim 18 and such amendments are fully supported by the specification and claims, as originally filed.

Rejection under 35 U.S.C. § 103 – Alleged Obviousness

Claims 18-20, 32, 33, 35, 36, and 38 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 5,248,310 (“the Barclay patent”) in view of U.S. Patent No. 5,785,994 (“the Wong patent”). Applicants respectfully traverse the rejection because combination of the respective teachings of these patents, even if motivated, would not have produced any claimed method.¹

Each of claims 18-20, 32, 33, 35, 36, and 38 is directed to methods that involve, *inter alia*, the steps of: (1) compressing a first layer containing a drug ingredient, a second layer containing a drug ingredient, and a third layer that does not contain a drug ingredient, thereby forming a “drug/drug/no drug” three-layer structure; and (2) detecting the formulation orientation of a tablet using a color detector directed at a spot location on the side of the tablet.

¹ With respect to the issue of motivation, the Office Action misstates the requirements for establishing a *prima facie* case of obviousness. Although the Office Action asserts that “for obviousness under § 103, all that is required is a reasonable expectation of success” (Office Action at page 7), much more is required. Specifically, an examiner seeking to enter a rejection for alleged obviousness must additionally identify some suggestion or motivation to combine references or otherwise modify their teachings. MPEP § 2142.

A person of ordinary skill seeking to combine the cited teachings of the Barclay and Wong patents would not have produced such a method. The Office Action, for example, fails to identify any disclosure in the patents relating to a mechanical color detector, or of using a color detector to detect the formulation orientation of a tablet. Thus, this aspect of the claims would be absent from any method that those of ordinary skill might theoretically produce by combining the patents' cited teachings.

The patents also lack any disclosure of Applicants' compression step. Acknowledging that the dosage form disclosed by the Barclay patent has a different structure than those produced by Applicants' claimed methods, the Office Action alleges that it would have been obvious to those of ordinary skill to instead employ the structure disclosed by the Wong patent (Office Action at page 4). Significantly, however, although the Wong reference discloses a three-layer dosage form, the orientation of those layers differs from the orientation recited in the instant claims. The Office Action, for example, refers to the dosage form described at column 17, which has a "no drug/drug/no drug" structure that is said to be formed by disposing a single drug-containing layer between two layers that do not contain a drug (Wong patent at column 17, lines 34-43). Thus, whereas the claimed methods yield a "drug/drug/no drug" structure, the proposed combination of the Wang and Barclay patents would yield a *different* structure, having the "no drug/drug/no drug" orientation.

Since combination of the Wong and Barclay patent in the manner proposed would not have produced any of the claimed inventions, the rejection for alleged obviousness is improper and should be withdrawn. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a *prima facie* case of obviousness).

Objection to Claims 34 and 37

The Office has objected to claims 34 and 37 as being dependent upon a rejected base claim. Applicants respectfully submit that because applicants have demonstrated that the rejected claims upon which claims 34 and 37 depend are in condition for allowance, the objection to dependent claims 34 and 37 should be withdrawn.

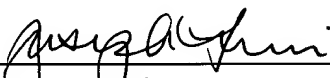
DOCKET NO.: ARC-2865-R3/ALZA-0022
Application No.: 09/324,343
Office Action Dated: 8/24/2005

PATENT

Conclusions

In view of the above, applicants respectfully request: (1) entry of the amendment to claim 18, and (2) reconsideration and withdrawal of the rejection of claims 18-20 and 32-38, and of the objection to claims 34 and 37, as well as allowance thereof. If the Examiner is of a contrary view, the Examiner is invited to contact the undersigned attorney at (215) 568-3100.

Date: November 22, 2005



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